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DATE MAILED: 03/15/2010

## NOTICE OF ALLOWANCE AND FEE(S) DUE

24353 7590 03/15/2010
BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
FAST PALO ALTO CA 943/03

EXAMINER					
CAMPBELL, VICTORIA P					
ART UNIT	PAPER NUMBER				
3763	•				

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/596,207	08/21/2007	Jeffrey A. Schuster	ZGNX-112	3424	
TITLE OF INVENTION: DEVICE FOR READYING A NEEDLE FREE INJECTOR FOR DELIVERY					

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	06/15/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FFE: shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

## PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

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1900 UNIVERS SUITE 200					Lber	Cert	tificate	of Mailing or Trans	
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nonprovisional	YES		\$755	\$300		\$0		\$1055	06/15/2010
EXAM	EXAMINER ART U		T UNIT	CLASS-SUBCLASS					
CAMPBELL, VICTORIA P 3763		3763	604-068000	_					
"Fee Address" ind PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A	ondence address (or Cha 3/122) attached. ication (or "Fee Address 2 or more recent) attach ND RESIDENCE DATA ess an assignee is ident h in 37 CFR 3.11. Comp	nge of Con "Indication ed. Use of	respondence  form Customer		ingle or a attor Il be p or typ he pa g an a	ely,  elifim (having as a gent) and the name neys or agents. If i printed.  e)  utent. If an assigne ussignment.	memb es of u no nam ee is id	er a 2	ocument has been filed for
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Authorized Signature						Date			
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## UNITED STATES PATENT AND TRADEMARK OFFICE

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# Determination of Patent Term Extension under 35 U.S.C. 154 (b)

(application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

# Notice of Allowability

Application No.	Applicant(s)
10/596,207	SCHUSTER ET AL.
Examiner	Art Unit
VICTORIA P. CAMPBELL	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- This communication is responsive to 10/23/09.
- The allowed claim(s) is/are 1,6,9-13 and 28.
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  $\square$  All b) ☐ Some\* c) ☐ None of the:
    - 1. T Certified copies of the priority documents have been received.
    - 2. Certified copies of the priority documents have been received in Application No.
      - 3. 
        ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) hereto or 2) to Paper No./Mail Date
  - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of

each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. 

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- 1. Notice of References Cited (PTO-892)
- 2. Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08).
- Paper No./Mail Date 10/23/09
- 4. T Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date
- 7. X Examiner's Amendment/Comment
- 8. X Examiner's Statement of Reasons for Allowance
- 9. ☐ Other

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## DETAILED ACTION

## EXAMINER'S AMENDMENT

 An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in two telephone interviews with Karl Bozicevic (Reg. No. 28,807) on March 1, 2010 and March 4, 2010.

The application has been amended as follows:

# IN THE CLAIMS:

Claim 1: A device, comprising:

A needle-free injector comprised of an injection orifice;

a cap covering the injection orifice of the injector:

a mechanism for changing the injector from a safe position to a ready position to a triggering position;

wherein the cap is positioned such that the cap must be removed before the injector is placed in the ready position;

wherein the mechanism for changing the injector from the safe position to the ready position comprises a latch and wherein the device further comprises a mechanism for moving the latch from a latch safe position to a latch ready position, wherein the mechanism for moving the latch comprises a pin and a means for actuating

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the pin, wherein, upon actuating the pin, the pin pushes the latch from the latch safe position to the latch ready position; and

wherein the means for actuating the pin comprises a lever movable from a lever safe position to a lever ready position, and a collar at least partially encircling the injector, wherein actuating the lever moves the collar which moves the pin against the latch wherein the latch is moved from the latch safe position to the latch ready position.

Claim 4: CANCELLED

Claim 5: CANCELLED

Claim 6: The device as claimed in <u>claim 1</u> [[4]], wherein the mechanism for changing the injector from the safe position to a ready position to a triggering position further comprises:

an additional safety mechanism to prevent triggering of the injector;

wherein moving of the lever from the lever safe position to the lever ready position removes moves the collar; and

wherein the additional safety mechanism is disengaged when the collar moves under the action of the lever moving from the [[safe]] lever <u>safe</u> position to the [[ready]] lever <u>ready</u> position.

Claim 10: The device as claimed in claim [[5]] 1, wherein the mechanism comprises a lever, [...].

Claim 11: The device as claimed in claim 1, wherein the mechanism comprises a lever, wherein the lever is movable only after the cap is removed, wherein rotating the lever places the injector in the ready position.

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Claim 12: The device of claim 1, wherein the device comprises a lever, and the an end of the lever is attached to the cap, and [[the]] a base of the lever actuates [[the]] a safety mechanism.

Claim 13: The device of claim [[5]] 1, configured such that [...].

Claim 28: The device as claimed in claim [[4]] 1, wherein the mechanism for changing the injector from the safe [[state]] <u>position</u> to the ready to deliver state <u>position</u> further comprises:

an additional safety mechanism to prevent triggering of the injector wherein the additional safety mechanism is disengaged when the lever is actuated.

# Allowable Subject Matter

- Claims 1, 6, 9-13, and 28 as amended by applicant October 23, 2009 and in the Examiner's Amendment above are allowed over the prior art of record.
- 3. The following is an examiner's statement of reasons for allowance: The claims in this application have been allowed because the prior art of record fails to disclose either singly or in combination the claimed device comprising a needle-free injector comprised of an injection orifice, a cap, and a mechanism for changing the injector from a safe position to a ready position to a triggering position, wherein the cap must be removed before the injector is placed in a ready position, and wherein the mechanism comprises a latch, a mechanism for moving the latch comprising a pin and a means for actuating the pin, and the means for actuating the pin comprise a lever and a collar at least partially encircling the injector, wherein actuating the lever moves the collar which

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moves the pin against the latch wherein the latch is moved from a latch safe position to a latch ready position.

- The closest prior art of record is Landau (USPGPub 2003/0093030 A1), however
  this reference does not teach or disclose the device as claimed or described above.
- 5. Regarding independent claims 1, the prior art of record fails to teach among all the limitations or render obvious a mechanism for changing the injector from a safe position to a ready position to a triggering position, wherein the means for actuating the pin comprise a lever and a collar at least partially encircling the injector, wherein actuating the lever moves the collar which moves the pin against the latch wherein the latch is moved from a latch safe position to a latch ready position.
- 6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance"

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell Examiner, AU 3763

/Nicholas D Lucchesi/ Supervisory Patent Examiner, Art Unit 3763